PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

Ström & Gulliksson IPC AB
Box 4188
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PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	01-07-2005
Applicant's or agent's file reference: W 5529-001 EK	IMPORTANT NOTIFICATION

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/SE2004/000755	14-05-2004	14-05-2003

Applicant
SpectraCure AB
et al

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in som Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the *PCT Applicant's Guide*.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, intentive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed invention is patentable or not" (see Also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the IPEA/	Authorized officer
Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. 08-667 72 88 Telex 17978 PATOREG-S	Seija Kurvi Telephone No. 08-782 25 00

Form PCT/IPEA/416 (January 2004)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference W 5529-001 GA/JW	**FOR FURTHER ACTION** See Form PCT/IPEA/416	
International application No. PCT/SE2004/000755	International filing date *(day/month/year)* 14.05.2004	Priority date *(day/month/year)* 14.05.2003
International Patent Classification (IPC) or national classification and IPC A61N5/01, A61B18/22		
Applicant SpectraCure AB et al		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:

   a. ☒ *(sent to the applicant and to the International Bureau)* a total of 8 sheets, as follows:

      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))

      _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☒	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☒	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
13.12.2004	17.06.2005
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. +46 8 667 72 88	Authorized officer Johanna Schyberg/EK Telephone No. +46 8 782 25 00

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/SE2004/000755

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1(b))
☐ publication of the international application (under Rule 12.4)
☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

☐ the international application as originally filed/furnished

☒ the description:

pages 1-30 as originally filed/furnished
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____

☒ the claims:

pages _____ as originally filed/furnished
pages* _____ as amended (together with any statement) under Article 19
pages* 1-8 received by this Authority on 08.06.2005
pages* _____ received by this Authority on _____

☒ the drawings:

pages 5 as originally filed/furnished
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____
☐ the sequence listing *(specify)*: _____
☐ any table(s) related to the sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____
☐ the sequence listing *(specify)*: _____
☐ any table(s) related to the sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
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Box No. II Priority

1. ☒ This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:

   ☒ copy of the earlier application whose priority has been claimed (Rule 66.7(a)).

   ☐ translation of the earlier application whose priority has been claimed (Rule 66.7(b)).

2. ☐ This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rule 64.1). Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

The priority is valid for those parts of the application which relate to the Swedish priority document. The US priority has not been checked since the ISA does not have access to that priority document.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 24-25

because:

☒ the said international application, or the said claims Nos. 24-25 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

See PCT Rule 67.1.(iv).: Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods.

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in the Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/SE2004/000755

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-23	YES
	Claims	---	NO
Inventive step (IS)	Claims	1-23	YES
	Claims	---	NO
Industrial applicability (IA)	Claims	1-23	YES
	Claims	---	NO

2. Citations and explanations (Rule 70.7)

Reference is made to the following document/documents cited in the International Search Report:
D1: EP0523417 A1
D2: EP0280397 A2
D3: WO02074339 A1
D4: JP4343317 A

Additional documents not cited in the International Search Report:
D5: Johansson T et al, "Feasibility study of a system for combined light dosimetry and interstitial photodynamic treatment of massive tumors", Applied Optics, United States, 2002

The invention concerns a system for interactive interstitial photodynamic and photothermal tumour therapy and tumour diagnosis and solves the problems related to switching between different operation modes in such a system.

D1-D4 represent the general state of the art of the invention.

The document D5 is regarded as being the closest prior art to the subject-matter of claims 1-23 and shows integration of optical dosimetry and diagnosis in an interstitial photodynamic treatment system.

The subject-matter of claims 1-23 therefore differs from this known system in that it discloses an optical switch involving translatory movement, which enables switching between

.../...

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
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Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date (valid claim) *(day/month/year)*
WO 03041575 A1	22.05.2003	11.11.2002	14.11.2002
EP 1314451 A1	28.05.2003	23.11.2001	23.11.2001

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure *(day/month/year)*	Date of written disclosure referring to non-written disclosure *(day/month/year)*

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of: Box V

different operation modes.

The subject-matter of claims 1-23 is therefore novel (Article 33(2) PCT).

The problem to be solved by the present invention may therefore be regarded as providing efficient and compact switching in a system according to D5.

The solution to this problem proposed in claims 1-23 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

- Claims 1-23 suggest a switch involving translatory elements to which optical fibres are attached. By providing translatory movement to the translatory elements, different fibres can be aligned to each other. Such a switch has not been suggested before within the area of endoscopes.
- Integrating such a switch in an endoscope provides a simple, secure and compact switching. It also enables the combination of several switches in one endoscope, e.g. for switching between light sources.
- The cited prior art does not give any indication that would lead a person skilled in the art to the claimed optical switch. Therefore, the claimed invention is not obvious to a person skilled in the art.

Accordingly, the invention defined in claims 1-23 is considered to involve an inventive step. The invention is industrially applicable.

PCT/SE2004/000755
08-06-2005
10/556806

AMENDED CLAIMS 2005-06-08 (755)

1. A system for interactive interstitial photodynamic or photothermal tumour therapy or tumour diagnosis of a human, comprising;

at least one first light source for emission of light within the wavelength-range of infrared (IR) visible or ultraviolet light;

at least one light detector, for detection of light; and

a plurality of optical fibres adapted to conduct light to or from a tumour site at or in said human, wherein the optical fibre is in use employed as a transmitter or a receiver for conduction of light to or from the tumour site for therapy or diagnosis of a tumour at the tumour site;

characterised by

at least one distributor adapted to distribute said light from at least the first light source to the tumour site, wherein the distributor comprises at least one longitudinal translatory element having a plurality of said optical fibres attached thereto and being arranged in such a manner that light is coupled in different constellations to or from said optical fibres for a diagnostic or a therapeutic mode of said system by longitudinal translatory movement of said longitudinal translatory element between pre-determined positions for aligning said optical fibres with a corresponding coupling element for transmitting or receiving said light to or from said light source or said light detector.

2. The system according to claim 1, wherein said system comprising at least one second light source for emission of therapeutic light through at least one of said optical fibres via said distributor via said longitudinal translatory element and said corresponding opposing coupling element to said tumour site.

3. The system according to any of the previous claims, **characterised** by

a plurality of first optical fibres arranged for conducting light to or from the tumour site,

a plurality of second optical fibres arranged for delivering light from at least one light source or transmission of light to said at least one light detector, and

wherein said distributor is a distributor for distribution of light from at least one light source to the tumour site and/or from the tumour site to said least one light detector, wherein the opposing coupling element is a second longitudinally translatory element, and being arranged in such a manner that light is coupled in different constellations by translatory movement of a first of said translatory elements between pre-determined positions relative to the other said translatory elements.

4. The system according to claim 3, **characterised** in that each translatory element has holes arranged for receiving said optical fibres and that corresponding holes on the two translatory elements are equidistantly arranged on a straight line, and wherein said translatory elements

are configured for transmitting light between the translatory elements.

5. The system according to claim 4, **characterised** in that first ends of the first optical fibers are fixed in the holes of a translatory displacement element and first ends of second optical fibres are fixed in the holes in the second translatory element, wherein the first and the second optical fibres are connectable to each other in different constellations through said longitudinal translatory movement between pre-determined positions of the longitudinal translatory displacement element and the second translatory element relative each other.

6. The system according to claim 1, **characterised** by further comprising two flat discs in close proximity to each other, wherein said discs are turnable relatively to each other,

each disc having holes arranged on a circular line, wherein the circle radius on one disc equals the circle radius on the other disc and where the holes in one disc are equally distributed on a circle line with an angular separation of $v_1=(360/n_1)$ degrees, n_1 being the number of holes, and the holes in the other disc are equally distributed on the circle line with an angular separation of $v_2=(360/n_2)$ degrees, wherein $n_2 = m \times n_1$, and wherein m is a multiple, which yields n_2 as an integer ≥ 1, and

wherein first ends of third optical fibres are fixed in the holes of the first disc and first ends of fourth optical fibres are fixed in all holes of the second

disc except for one, whereby the third and the fourth optical fibres by rotation of the turnable disc relative to the other disc are connectable to each other in different constellations,

and wherein said longitudinal translatory element is arranged substantially radially outwards movable and integrated with said other disc to couple between a plurality of said first optical fibres to one of said third optical fibres.

7. The system according to claim 6, **characterised** by n_1 being the number of holes in the first disc of the distributor, $n_1 = 6$ and $m = 2$, yielding $n_2 = 12$ holes in the second disc of the distributor.

8. The system according to claim 6 or 7, **characterised** by every other fourth optical fibre being part of a first series of fourth optical fibres and that an optical fibre conductor in said first series of fourth optical fibres conductors being arranged for emitting light from the light source and the other optical fibres in said first series of fourth light conductors being arranged for transmission of light to the light detector.

9. The system according to claim 7 or 8, **characterised** in said first optical fibres being connected to diagnostic light sources, such that the longitudinal translatory element in said other disc couples one of said diagnostic light sources to one of said third optical fibres in said first disc.

10. The system according to any of the previous claims, **characterised** by the diagnostic light source comprising a beamsplitter.

11. The system according to claim 10light fibre being arranged between a dichroic beamsplitter and the light detector.

12. The system according to claim 11 or 12, **characterised** by fluorescence being recorded through the same optical fibre as the one transmitting light to the tumour site.

13. The system according to claim 1, **characterised** by the third optical fibres second ends being treated by a material with temperature sensitive fluorescence emission.

14. The system according to claims 6 or 7, **characterised** by every second of said fourth optical fibres being part of a second series of fourth optical fibres arranged for emission of light from the light source.

15. The system according to any of claims 2 to 14, **characterised** by the therapeutic light source being a light source for coherent light of a single fixed wavelength.

16. A system according to any of the previous claims, **characterised** by the distributor including means for locking the light distributor into pre-determined transversal and/or azimutal positions.

17. The system according to claim 13, **characterised** in that one or several of the optical fibres which are treated with the material with a temperature sensitive fluorescence emission are in use measuring the temperature at the tumour site,

that the light which is sent to the tumour site in use is heating the tumour site, and

that the intensity of the light is controllable by the measured temperature in order to regulate the temperature of the tumour site at the individual optical fibres.

18. The system according to any of the previous claims, **characterised** in that said longitudinal translatory displacement element is an optical sledge.

19. The system according to any of the previous claims, **characterised** by at least one stepping motor or at least one servo system for moving said elements of said light distributor relative each other.

20. The system according to any of the previous claims, **characterised** in that said operation modes are modes of the system comprised in the list of: interactive interstitial photodynamic tumour therapy, photothermal tumour therapy using hyperthermia, and tumour diagnostics,

whereby these operation modes in use are alternated during the same occasion of treatment of said tumour site.

21. The system according to any of claims 2 to 20, **characterised** by said operation modes of said system comprising

a diagnostic operation mode, wherein one diagnostic light source is coupled via a first longitudinal translatory element to said first optical fibres transmitting diagnostic light to said site and the remaining first optical fibres are coupled to a light detector, and

a therapeutic operation mode, wherein said therapeutic light sources are coupled to said first optical fibres transmitting therapeutic light to said site.

22. The system according to claim 21, **characterised** in that at least one second longitudinal translatory element switches between the operating modes.

23. The system according to claim 22, **characterised** in that a third longitudinal translatory element is configured to switch between a plurality of optical fibres from said second longitudinal translatory element to said light detector.

24. A method for interactive interstitial photodynamic tumour therapy or photothermal tumour therapy or tumour diagnosis of a human, wherein at least one light detector and a plurality of optical fibres are connected to a tumour site and the optical fibres are used as a

transmitter or a receiver for conduction of light to or from a tumour site for diagnosis and therapy of a tumour at the tumour site,

characterised in that the switching between tumour therapy and tumour diagnostics is achieved in an automatised way by switching light fibres between different constellations by means of a light distributor comprised in the system according to any of claims 1 to 23, and

that the results from the diagnostics control the therapy process by regulating a therapeutical light intensity depending on the results of the diagnostics until an optimal treatment of the tumour site is achieved.

25. The method according to claim 24, **characterised** by alternatingely utilising interactive interstitial photodynamic tumour therapy, photothermal tumour therapy using hyperthermia, and tumour diagnostics during the same occasion of treatment of said tumour site.